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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/054,567	11/13/2001	Christel Schmelzer	1/1171	7734
28501	7590	12/24/2003	EXAMINER	
BOEHRINGER INGELHEIM CORPORATION			TRAVERS, RUSSELL S	
900 RIDGEBURY ROAD			ART UNIT	
P. O. BOX 368			PAPER NUMBER	
RIDGEFIELD, CT 06877			1617	

DATE MAILED: 12/24/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/054,567	Applicant(s) SCHMELZER ET AL.	
	Examiner Russell Travers, J.D., Ph.D	Art Unit 1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-46 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-46 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
 * See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
 a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>4</u> . | 6) <input type="checkbox"/> Other: _____ |

Art Unit:

Claims 1-46 are presented for examination.

The amendment filed March 22, 2002 has been received and entered into the file

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 43 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Examiner notes claims 43 requires an inhaler set forth in an issued WIPO patent. This object is critical to practicing the invention as claimed. Information critical to practicing a claimed invention can only be incorporated by reference to an issued US patent.

The following is a quotation of 35 U.S.C. § 103 which forms the basis for all obviousness rejections set forth in this Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains.

Art Unit:

Patentability shall not be negated by the manner in which the invention was made.

Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

Claims 1-12, 14-22, 26-42 and 45-46 are rejected under 35 U.S.C. § 103 as being unpatentable over Hochrainer et al and Wolf et al.

Hochrainer et al and Wolf et al teach the claimed tiotropium and salmeterol respectively as old and well known in combination with various pharmaceutical carriers and excipients in both a powder and liquid form useful for atomization. Hochrainer et al teach tiotropium and other asthma, and COPD medicaments in combination with polyalcohols, (page 5), EDTA (page 5, line 26), benzalkonium chloride (page 5, line 66), vitamin C (page 4, line 58). These compositions are taught in the particle size range ((970) page 5, line 10-15), pH ((970) page 4, line 60-62) and encapsulation schema herein envisioned. These pharmaceutical formulations are taught as useful for treating COPD and asthma, viewed by the skilled artisan as indistinguishable from that use herein claimed. Claims 1-12, 14-22, 26-42 and 45-46, and the primary references, differ as to:

- 1) the concomitant employment of these medicaments, and
- 2) administration levels of the medicaments.

Art Unit:

It is generally considered prima facie obvious to combine compounds each of which is taught by the prior art to be useful for the same purpose, in order to form a composition which is to be used for the very same purpose. The idea for combining them flows logically from their having been used individually in the prior art. As shown by the recited teachings, the instant claims define nothing more than the concomitant use of conventional anti-asthma agents. It would follow that the recited claims define prima facie obvious subject matter. Cf. In re Kerhoven, 626 F.2d 848, 205 USPQ 1069 (CCPA 1980).

Determining the active ingredient dosage level required to effect optimal therapeutic benefit is well within the Skilled Artisan's purview and the benefits of achieving such maximization obvious, to said skilled artisan. The claims merely recite the obvious employment of old and well known active ingredients, carriers and excipients. Thus, the only issue presented in the instant application is the obviousness of the claimed pharmaceutical compositions and therapeutic methods.

Claims 13, 23-24 and 25 are rejected under 35 U.S.C. § 103 as being unpatentable over Hochrainer et al and Wolf et al as set forth above for claims 1-12, 14-22, 26-42 and 45-46, in view of Weil et al.

Weil et al teach various anti-asthmatic medicaments, to include salmeterol, as old and well known in combination with various pharmaceutical carriers and excipients

Art Unit:

in both a powder and liquid form useful for atomization. Additionally, Weil et al teach those propellant gases herein claimed, to include TG 11(column 1, line 39) and butane (column 2, line 10) as old and well known with various medicaments as useful for treating asthma, and COPD. Claims 13, 23-24 and 25, and the primary reference, differ as to:

- 1) the concomitant employment of these medicaments and propellents

It is generally considered prima facie obvious to combine compounds each of which is taught by the prior art to be useful for the same purpose, in order to form a composition which is to be used for the very same purpose. The idea for combining them flows logically from their having been used individually in the prior art. As shown by the recited teachings, the instant claims define nothing more than the concomitant use of conventional anti-asthma agents and administration excipients. It would follow that the recited claims define prima facie obvious subject matter. Cf. In re Kerhoven, 626 F.2d 848, 205 USPQ 1069 (CCPA 1980).

Claims 43-44 are rejected under 35 U.S.C. § 103 as being unpatentable over Hochrainer et al and Wolf et al as set forth above for claims 1-12, 14-22, 26-42 and 45-46, in view of Applicants' admission on the record.

Art Unit:

Applicants admit on the record (see specification page 14) those devices herein claimed as old and well known for atomizing various pharmaceutical compositions of matter. Claims 43-44, and the primary reference, differ as to:

1) the concomitant employment of these medicaments in a conventional delivery system.

Claims 43-44 specifically require a device to spray various pharmaceutical compositions. Applicants admit on the record the claimed device as old and well known for the use herein envisioned. The skilled artisan would have seen spray administered compositions, and the administration of these compounds by spraying as residing in the skilled artisan purview.

No claims are allowed.

Any inquiry concerning this communication should be directed to Russell Travers at telephone number (703) 308-4603.



Russell Travers J.D., Ph.D.
Primary Examiner
Art Unit 1617